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Proposed Maximum Residue Limit PMRL2015-04

Difenoconazole

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on Crop Subgroup 20A (Rapeseed) to the product label of Inspire Fungicide, containing technical grade difenoconazole, is acceptable. The specific uses approved in Canada are detailed on the label of Inspire Fungicide, *Pest Control Products Act* Registration Number 30004.

The evaluation of this difenoconazole application indicated that the end-use product has merit and value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for difenoconazole is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace or be added to the MRLs already established for difenoconazole, are as follows.

Table 1 Proposed Maximum Residue Limits for Difenoconazole

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Difenoconazole	1-[[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole	0.1	Borage seeds, cuphea seeds, echium seeds, flaxseeds, gold of pleasure seeds, hare's ear mustard seeds, milkweed seeds, mustard seeds (condiment and oilseed types)[2], oil radish seeds, poppy seeds, rapeseeds (canola)[3], sesame seeds, sweet rocket seeds

[1] ppm = parts per million
[2] The MRL replaces the previously established 0.05 ppm MRL for mustard seeds.
[3] The MRL replaces the previously established 0.03 ppm MRL for rapeseeds (canola).

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for difenoconazole in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Borage seeds	0.1	Not established	Not established
Cuphea seeds	0.1	Not established	Not established
Echium seeds	0.1	Not established	Not established
Flaxseeds	0.1	Not established	Not established
Gold of pleasure seeds	0.1	Not established	Not established
Hare's ear mustard seeds	0.1	Not established	Not established
Milkweed seeds	0.1	Not established	Not established
Mustard seeds (condiment and oilseed types)[1]	0.1	Not established	Not established
Oil radish seeds	0.1	Not established	Not established
Poppy seeds	0.1	Not established	Not established

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Rapeseeds (canola)[2]	0.1	0.01 (canola seed)	0.05 (rape seed)
Sesame seeds	0.1	Not established	Not established
Sweet rocket seeds	0.1	Not established	Not established

[1] The MRL replaces the previously established 0.05 ppm MRL for mustard seeds.
[2] The MRL replaces the previously established 0.03 ppm MRL for rapeseeds (canola).

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for difenoconazole up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data from field trials conducted in Canada were submitted to support the domestic use of Inspire Fungicide on crops in Crop Subgroup 20A (Rapeseed). Difenoconazole was applied to canola at label rates, and harvested according to label directions. In addition, a processing study in treated canola was submitted to determine the potential for concentration of residues of difenoconazole into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for difenoconazole was based upon the submitted canola field trial data (which is the representative commodity of CSG20A), and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for canola (which was extended to all commodities in CSG20A).

Table A1 Summary of Field Trial and Processing Data Used to Support MRLs

Commodity	Application Method/ Total Application Rate (kg a.i. /ha)[1]	Pre-Harvest Interval (days)	Minimum Residues (ppm)	Maximum Residues (ppm)	Experimental Processing Factor
Canola seed	Foliar broadcast/ 115.7-137.09	29-35	<0.01	0.081	No concentration of residues in refined oil (<1x).

[1] kg a.i./ha - kilogram active ingredient per hectare

No significant increase to the dietary burden of livestock is anticipated from the use of Inspire Fungicide on crops in Crop Subgroup 20A (Rapeseed).

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of difenoconazole. Residues of difenoconazole in these crops at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.